



NOV - 6 2007

Stephen B. Davis  
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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,206,244

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,206,244, claims of which cover the human drug product BARACLUDE® (entecavir), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,587 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,587 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 23, 2007 (72 Fed. Reg. 8181). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2811 - 0) + 182 \\ &= 1,587 \text{ days (4.3 years)}\end{aligned}$$

Since the regulatory review period began January 19, 1997, after the patent issued (April 27, 1993), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

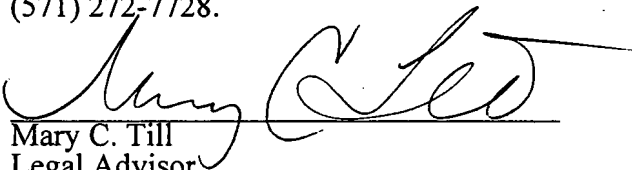
U.S. Patent No.:	5,206,244
Granted:	April 27, 1993

Original Expiration Date<sup>1</sup>: October 18, 2010  
Applicant: Robert Zahler and William A. Slusarchyk  
Owner of Record: Bristol-Myers Squibb Company  
Title: Hydroxymethyl (Methylenecyclopentyl) Purines and Pyrimidines  
Product Trade Name: BARACLUDE® (entecavir)  
Term Extended: 1,587 days  
Expiration Date of Extension: February 21, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE      By FAX: (571) 273-7728  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.



Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
HFD - 7  
5600 Fishers Lane (Rockwall II Rm. 1101)  
Rockville, MD 20857

RE: BARACLUDE® (entecavir)  
FDA Docket No.: 2006E-0356

Attention: Beverly Friedman

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).